

Introduction for Clinical Research Staff

Programme Day One

Subject to change

- 09.00 – 09.10 **Registration**
- 09.10 – 09.30 **Introduction to course**
Jenny Green, Education Team, Cambridge Clinical Research Centre
- 09.30 – 10.30 **Ethics and the Law in Clinical Research**
Tracey Hensman, Solicitor Consultant, R&D Department, CUHFT
- A brief history of research ethics
 - The key legal points relevant to clinical research staff
 - Obtaining ethical approval
- 10.30 – 10.45 Break
- 10.45 – 12.00 **Research Governance, HRA and the MHRA**
Tracy Assari, Research Governance Manager, R&D, CUHFT
- 12.00 – 12.45 **Data & Information Governance in clinical research**
Belinda Bruty, CUH Information Governance Support Manager
- 12.45 – 13.45 Lunch
- 13.45 – 14.15 **ABC of costing and funding for NIHR Portfolio studies – your role**
Christian Sparke, NIHR Support Manager
- 14.15 – 14.45 **Introduction to Public and Patient Involvement in clinical research**
Caroline McMahon, PPI Lead, Cambridge Clinical Research Centre
- 14.45 – 15.30 **Optional Session: Tour of the CCRC**
Stewart Fuller, Head Nurse, Cambridge Clinical Research Centre

Day one is facilitated by Jenny Green, CCRC Education Team

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Programme Day Two (draft) (optional depending on role)

- 09.00 – 09.15 **Registration**
- 09.15 – 09.30 **Introduction**
- 09.30 – 10.30 **Study Set-up and Management- What do you need to consider before you start?**
- The protocol
 - Study feasibility
- 10.30 – 11.00 Break
- 11.00 – 13.00 **Study Recruitment**
- Recruitment and retention
 - Informed consent
- Study management**
- Key study personnel and delegation of duties
 - Study data and completing case report forms
 - Managing study medicines
 - Blood tests and labs
- 13.00 – 14.00 Lunch
- 14.00 – 15.00 **Study management session 2**
- Safety reporting
 - Monitoring, audit and the MHRA
 - Closing your study
- 15.00 – 15.30 **Q&A session and close**

Day two is facilitated by Alexandra Malyon, ReSPECT Specialist Nurse / Clinical Research Development Nurse